

# Innovative Medical Plastic Molding: The Fastest Path to Saving Lives



All too often, American patients are receiving substandard treatment when they are at their most vulnerable: more than half of IV medication is administered incorrectly, and more than half of those errors result from poor labeling. These errors can be fatal. Compounding the problem, many clinicians have reported that poor labeling has kept them from responding quickly enough to save a patient in crisis. These deaths are not the fault of poorly trained clinicians but inadequate technology. All infusion therapy lines look alike, and no effective IV-line identification system has been established.

That's why Sāfen Medical developed a new tagging system to solve this problem and bring better care to patients nationwide. To do so, they leveraged the power of medical plastic molding in collaboration with SigmaPro.

Here's how.



## Problem

Sāfen designed an IV line communication system that uses shape, color, icon and haptics. The tag shape and color indicates drug category: e.g. the triangles indicate ISMP (Institute for Safe Medical Practice) High Alert Medications. Each tag also has an icon and word on its front to communicate the line's type of contents ("Opioid"), and room on the back for specifics ("fentanyl"). These features make it easy for a clinician, faced with an emergency, to tell immediately which line is which instead of trying to sort through a tangle of lines.

But in prototyping Sāfen struggled with certain problems. Which material would withstand hospital disinfectants, for example, and which type of printing would be legible but would not fade after regular handling? What design would permit the tag to attach easily to an IV line but would not fall off or occlude the line? How much pressure should be required to close a tag? Answering these questions required the kind of expertise in medical plastic molding only an expert like SigmaPro could provide.



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## The Collaboration

Solving these problems didn't just require an experienced FDA-registered medical plastic molding supplier with a proven record of successful manufacturing and excel under strict documentation and process validation conditions. It required a proactive design partner that brought a yes-we-can spirit to every single challenge. When Sāfen showed SigmaPro a prototype that was only partially functional, SigmaPro saw how to make it work—and then proved they could do so through a series of iterative, collaborative designs that optimized for both manufacturability and functionality. SigmaPro's turnaround time for each model was no more than two weeks.

SigmaPro's speed and efficiency will ultimately save lives. Other providers of medical plastic molding would have gotten bogged down in the development stage, dragging the client through endless layers of red tape, reviews, and inefficient requirements that do not respect the pressure of the client's timeline. That process can take months or years and cost the client thousands of dollars—not to mention countless patient lives.

Sāfen found collaborating with SigmaPro to be so smooth and satisfying that Renae Franz, Chief Commercialization Officer at Sāfen with more than three decades of experience in medical device development, said the people at SigmaPro felt like part of her own team.

“We just had to tell them what we wanted to accomplish and SigmaPro found a way to make it work,” she said. “It was so refreshing to work with a supplier who always wanted to say yes.”



## The Result

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## The Result

SigmaPro successfully manufactured Sāfen's new tagging system—and did so far faster than initially anticipated. Ms. Franz estimated that, thanks to SigmaPro, Sāfen was able to bring the product to market six to twelve months sooner than they would have with any other supplier.

The tags SigmaPro is manufacturing are already performing well. In an initial study, clinicians were able to find the correct line twenty seconds faster than they could before—a potentially life-saving difference. In another preliminary study, clinicians were better able to identify and remedy errors in lines labeled with Sāfen tags than with existing tagging systems. Fortunately, SigmaPro has manufacturing capacity to dramatically scale up production at short notice as clinicians continue to recognize the transformative power of Sāfen's life-saving technology.



To discover more about medical plastic molding and how SigmaPro can help your company save lives, talk to one of our engineers today.

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